

# **EXHIBIT 1**

# AMERICAN FAMILY PHYSICIAN®

## Letters to the Editor

# No Data to Show Link Between Opioid Abuse and Heroin Use

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TO THE EDITOR: The Letter to the Editor, entitled "Probable Relationship Between Opioid Abuse and Heroin Use,"<sup>1</sup> in the March 1, 2003 issue of *American Family Physician*, reports data collected by the Ohio Substance Abuse Monitoring (OSAM) Network<sup>2</sup> suggesting that the abuse of opioid analgesics, namely OxyContin, constitutes a new route to heroin use. Although the mission of the OSAM Network is "to provide accurate epidemiologic descriptions of substance abuse trends and emerging problems in Ohio's major metropolitan and rural areas,"<sup>2</sup> there is a lack of the important information necessary to assess the validity of these findings. There is no description of the methods of recruitment or characteristics of the 10 participants (e.g., treatment-seeking status), and it is unclear whether a standardized assessment<sup>3</sup> was used to diagnose opioid analgesic abuse before participant initiation of heroin use. The authors appropriately point out the limitations of the small sample size. However, they defend this limitation based on anecdotal experience with patients who have transitioned from opioid analgesic abuse to heroin use, rather than through the use of statistical analysis to assess whether or not a trend exists.

Epidemiology on substance abuse trends requires a thorough description of methodology and analysis to inform the public and to guide health policy. While it may be tempting for the authors to attribute the rise in heroin abuse to increased prescription of OxyContin or other prescription opioids, this is not the case elsewhere; in New York City, where there has not been an increase in OxyContin problems, there has been a major increase in heroin abuse during the past decade.<sup>4</sup> Increased heroin potency during this time is believed to have made noninjecting routes more attractive, an explanation that also may be of more relevance elsewhere in the United States. While I agree with the authors' call for improved prevention programs for young people and physicians about prescription drug abuse, their data as presented in their letter<sup>1</sup> do not support a link between opioid analgesic abuse and subsequent heroin use.

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## REFERENCES [show all references](#)

1. Siegal HA, Carlson RG, Kenne DR, Swora MG. Probable relationship between opioid abuse and heroin use [letter]. *Am Fam Physician.* 2003;67:942,945....

IN REPLY: Dr. Gunderson questions the preliminary findings in our Letter to the Editor,<sup>1</sup> in which we suggested a probable link between increases of opioid abuse and subsequent heroin abuse. Our findings were based on qualitative data obtained from a small sample of young heroin users through the Ohio Substance Abuse Monitoring (OSAM) Network, a statewide system that uses multiple data sources to identify substance abuse trends.

Previous indications of increases in heroin abuse in Ohio motivated us to investigate the phenomenon more thoroughly. One purpose of the semistructured interview protocol was to understand pathways to heroin abuse. We reported that five of 10 subjects (ages 18 to 33 years) who participated in in-depth qualitative interviews in Dayton, reported abusing pharmaceutical opioids before abusing heroin. Dr. Gunderson is correct that we did not describe the recruiting of subjects in our letter. Participants in the study were recovering and active users recruited by community outreach workers using convenience methods. Previous dependence on pharmaceutical opioids was based on self-report rather than standardized assessment. The relationship between self-reported, initial dependence on pharmaceutical opioids (including OxyContin) and subsequent heroin abuse continues to be reported in Ohio areas of Columbus, Dayton, Akron-Canton, and Youngstown.<sup>2</sup>

We fear that Dr. Gunderson may have misinterpreted our observations as causal statements. OSAM and its federal counterparts (the Community Epidemiologic Work Group [CEWG] operated by the National Institute on Drug Abuse and "Pulse Check" operated by the Office of National Drug Control Policy) are "early warning systems" designed to alert the public health and practice communities to potential rapid changes in substance abuse behaviors. Qualitative methodologies are ideally suited to fulfill this function because, in comparison with expensive, long-term quantitative studies, they can quickly and relatively inexpensively provide preliminary indications of emerging trends.

Several national drug surveillance efforts identified similar trends in other parts of the nation; although, as Dr. Gunderson noted, such patterns have not yet appeared in New York City. For example, the CEWG identified a relationship between initial OxyContin abuse and subsequent heroin abuse in Boston<sup>3,4</sup> and non-metropolitan counties surrounding Atlanta.<sup>5</sup> The National Drug Intelligence Center reported that: "OxyContin abusers who have never used heroin may be

attracted to the lower priced heroin when their health insurance no longer pays for OxyContin prescriptions or when they cannot afford the high street-level price of OxyContin."<sup>10</sup>

The purpose of our Letter to the Editor<sup>1</sup> was not to attribute increases in heroin abuse to OxyContin specifically, or any other proprietary-name analgesic, but rather to encourage prevention, intervention, and research strategies concerning this newly emerging, potential pathway to heroin abuse. We also emphasize that the proper use of opioid analgesics for pain management is of paramount importance.

Based on preliminary findings from OSAM and the national surveillance systems, we are convinced that there is a probable relationship between this pattern of pharmaceutical opioid abuse and subsequent heroin abuse. Now is the time to initiate rigorous, large-scale, longitudinal epidemiologic research to fully describe this phenomenon. OSAM and similar efforts have indicated the directions for such confirmatory studies.

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1. Siegal HA, Carlson RG, Kenne DR, Swora MG. Probable relationship between opioid abuse and heroin use [letter]. *Am Fam Physician*. 2003;67:942,945....

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